IN THE UNITED STATES DISTRICT COURT FOR THE SOUTHERN DISTRICT OF INDIANA INDIANAPOLIS DIVISION

ELI LILLY AND COMPANY,)
Plaintiff, v.)) C.A. No. 1:10 CV-1376 TWP-DKL
v.) C.M. 100. 1.10 CV-1370 TW1-DKL
TEVA PARENTERAL MEDICINES, INC.,	,)
APP PHARMACEUTICALS, LLC,)
PLIVA HRVATSKA D.O.O.,)
TEVA PHARMACEUTICALS USA INC., and)
BARR LABORATORIES, INC.)
)
Defendants.)

BRIEF IN SUPPORT OF DEFENDANTS' CONSENTED TO MOTION FOR LEAVE TO AMEND THEIR PRELIMINARY INVALIDITY CONTENTIONS

Pursuant to Local Rule 15.1 and Paragraph U of the March 22, 2011 Case Management Plan, Defendants Teva Parenteral Medicines, Inc., APP Pharmaceuticals, LLC, Pliva Hrvatska d.o.o., Teva Pharmaceuticals USA, Inc., and Barr Laboratories, Inc. (collectively, "Defendants") submit this brief in support of Defendants' Consented To Motion For Leave To Amend Their Preliminary Invalidity Contentions. Defendants' proposed amendment will not require any changes to the current March 22, 2011 Case Management Plan concerning fact discovery, claim construction, or the subsequent dates for completion of this case.

Amendment of preliminary contentions may be made by order of the Court upon a showing of good cause. *See* March 22, 2011 Case Management Plan, ¶ U. Good cause for an amendment exists where the moving party acted diligently and there is no prejudice to the non-moving party. *See ATA Airlines, Inc. v. Federal Exp. Corp.*, No. 1:08-cv-0785-RLY-DML, 2009 WL 5173475, *1-2 (S.D. Ind. Dec. 22, 2009) (granting a motion for leave to amend to add an

affirmative defense after the date set in the Case Management Plan because the amending party had "good cause for the amendment," which the Court based "primarily [on] an examination of whether the moving party acted diligently", and the amendment did not unduly prejudice the non-amending party.) Here, Defendants' diligent and prompt actions in bringing this proposed amendment before the Court and the absence of any prejudice to Plaintiff demonstrate good cause for Defendants' Consented To Motion To Amend Their Preliminary Invalidity Contentions. Indeed, Plaintiff has consented to this motion.

I. DEFENDANTS ACTED DILIGENTLY AND HAVE DEMONSTRATED GOOD CAUSE TO AMEND THEIR PRELIMINARY INVALIDITY CONTENTIONS

On June 27, 2011, Defendants' served Plaintiff with their fifty-four page preliminary invalidity contentions. A few weeks later, in the course of diligently considering preliminary proposed constructions for the claim terms identified by the parties for possible construction in advance of the August 1, 2011 deadline for exchange of proposed constructions, Defendants recognized, for the first time, the existence of additional invalidity positions stemming from the construction of a particular claim term.

Defendants promptly contacted Plaintiff on July 21, 2011 at around 9:45 am to inform Plaintiff of this development and to request their consent to an amendment. Counsel for Plaintiff said that they would get back to counsel for Defendants. On July 25, 2011, Plaintiff asked for, and Defendants agreed to provide, more detail regarding Defendants' proposed amendment to their preliminary invalidity contentions. Just two days later, on July 27, 2011, Defendants provided Plaintiff with a copy of their proposed amendment to their preliminary invalidity contentions. On August 1, 2011, Plaintiff confirmed that it consented to Defendants' motion to amend their preliminary invalidity contentions in exchange for Defendants' agreement to a one month extension until September 2, 2011 for Plaintiff to identify an expert witness to address

claim construction issues raised by Defendants' proposed amendment. This extension for Plaintiff to identify an expert witness to respond to this amended position during claim construction will not otherwise impact the schedule for briefing or arguing claim construction.

Defendants' actions have been diligent and timely. Indeed, Plaintiff has consented to this motion. Therefore, Defendants have demonstrated good cause to amend their preliminary invalidity contentions.

II. DEFENDANTS' PROPOSED AMENDMENT TO THEIR PRELIMINARY INVALIDITY CONTENTIONS DOES NOT PREJUDICE PLAINTIFF

Defendants' proposed amendment to their preliminary invalidity contentions will not unfairly prejudice Plaintiff. As noted above, Plaintiff has already consented to Defendants' proposed amendment.

Defendants propose this amendment to their preliminary invalidity contentions early in litigation. Discovery is barely underway and the parties have not submitted proposed claim constructions to the Court. The deadline for serving final invalidity contentions is many months away. Significant time remains for fact discovery and in the claim construction process (with a *Markman* hearing to be held on approximately December 23, 2011) (*see* Case Management Plan, ¶ N), allowing Plaintiff ample time to address issues raised in Defendants' proposed amendment. Moreover, Defendants have agreed to a one month extension until September 2, 2011 for Plaintiff to identify an expert witness to address possible claim construction issues raised by Defendants' proposed amendment. The parties agree that no other adjustment to the schedule will be necessary.

In a recent case in this district, the Court allowed an amendment to an invalidity contention, even where the amendment occurred much later in the case. In *Eli Lilly v. Teva*, the Court permitted defendant Teva to argue an invalidity position in post trial briefing that did not

appear in Teva's **final** contentions because the evidence at trial put plaintiff on notice that Teva would make that argument. *Eli Lilly and Co. v. Teva Pharm. USA, Inc.*, 657 F. Supp. 2d 967, fn 54 (S.D. Ind. 2009) (emphasis added). Defendants' proposed amendment to their **preliminary** invalidity contentions at this very early stage of litigation will not prejudice Plaintiff.

For the foregoing reasons demonstrating good cause and lack of prejudice, Defendants respectfully request that the Court grant Defendants' Consented To Motion For Leave To Amend Defendants' Preliminary Invalidity Contentions.

Respectfully submitted,

s/ Kandi Kilkelly Hidde

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CERTIFICATE OF SERVICE

I certify that on August 3, 2011, a copy of the BRIEF IN SUPPORT DEFENDANTS' CONSENTED TO MOTION FOR LEAVE TO AMEND THEIR PRELIMINARY INVALIDITY CONTENTIONS was filed electronically. Notice of this filing will be sent to the following parties by operation of the Court's electronic filing system. Parties may access this filing through the Court's system:

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